

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 15 DEC 2005

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Applicant's or agent's file reference F18239 JAL	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/IB2004/002863	International filing date (day/month/year) 03.09.2004	Priority date (day/month/year) 09.09.2003
International Patent Classification (IPC) or national classification and IPC A61N2/00		
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- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 7 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☒ sent to the applicant and to the International Bureau a total of 2 sheets, as follows:
 - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains Indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 07.07.2005	Date of completion of this report 13.12.2005
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**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IB2004/002863

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-15 as originally filed

Claims, Numbers

1-27 received on 11.07.2005 with letter of 07.07.2005

Drawings, Sheets

1/10-10/10 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 22-27

because:

☒ the said international application, or the said claims Nos. 22-27 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 22-27

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-21
	No: Claims	
Inventive step (IS)	Yes: Claims	4
	No: Claims	1-3, 5-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**WRITTEN OPINION OF THE INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY
(SEPARATE SHEET)**

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Re Item III.

The method of treating a subject in need of enhanced sexual function as defined in claims 22-27 is regarded to be a method for therapeutic treatment of the human or animal body. Therefore, said claims have not been searched. Moreover, according to Article 34(4)(a)(i) PCT and Rule 67.1(iv) PCT, no international preliminary examination is required to be carried out on these claims.

Re Item V.

- 1 The following documents are referred to in this communication:

D1 : US 6 348 033 B1
D2 : GB 2 082 915 A
D4: Fr 2 554 355 A1
D5: US2004/152948 A1.

- 2 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

Document D4 is regarded as being the closest prior art to the subject-matter of claim 1 and discloses a device for implementing and maintaining an erection of the penis (i.e. treatment of impotence; see p. 1, l. 2-3), said device being shaped to receive a flaccid penis (p. 1, l. 22) and being of titanium metal (p. 1, l. 20); said device furthermore comprising at least one energy source in the form of at least one magnet (p. 1, l. 24-26). It should be noted that the **synergetic effect** of using both titanium and magnetism, on which the purported inventive idea appears to be based, is discussed in D4, see for example p. 1, l. 31-34.

The subject-matter of claim 1 therefore differs from this known device in that it comprises

a cuff.

The problem to be solved by the present invention may therefore be regarded as how to allow for extensive application of the beneficial effects in daily life, which is not possible with the device taught by D4, on which the patient sits, saddle like (p. 1, l. 30-32).

The solution proposed in claim 1 of the present application cannot be considered to involve an inventive step (Article 33(3) PCT), since a cuff has already been employed for the same purpose in a similar device (see the "penile band" having a "plurality of magnetic portions" in document D1, p. 1, l. 24-59). It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply this feature with corresponding effect to a device according to document D4, thereby arriving at a device according to claim 1.

3 DEPENDENT CLAIMS 2, 3, 5-21

Dependent claims 2, 3 and 5-21 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT).

Specific reference is made to a combination of D1 with D4 or D2 with D4. In particular, the inclusion of a further magnet according to claim 3 is also taught by D1 ("plurality of magnetic portions"). The sizes and magnetic flux densities defined in claims 6-13 merely amount to obvious design options out of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill.

4 DEPENDENT CLAIM 4

The subject-matter of claim 4 appears to meet the requirements of the PCT with respect to novelty and inventive step.

No prior art document published before the priority date of the present application suggests the inclusion of a bioceramic bead or any means for emitting infrared rays to the device defined in claim 1. The infrared rays emitted by the bead(s) upon thermal

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activation by body temperature are said to have a beneficial effect on the stimulated tissue, which cannot be contested.

Re Item VI.

Since the validity of the priority claimed seems to be questionable for at least some aspects of the present application, in particular for the features defined in claim 4, the relevance of document D5 with respect to its subject-matter is pointed out (see par. [0007] and [0009]).

Re Item VIII.

The features in device claims 2 and 17-19 relate to a method of using the device rather than clearly defining the device in terms of its technical features. The intended limitations are therefore not clear from these claims, contrary to the requirements of Article 6 PCT.

IB/04/2863

CLAIMS:

We claim:

1. A device for implementing and maintaining an erection of the penis, comprising:
a cuff shaped to receive a flaccid penis, the cuff being of titanium-metal; and
at least one energy source in the form of at least one magnet.
2. The device according to claim 1, wherein the cuff has inside and outside surfaces, the magnet being positioned so that southern pole of the magnet, in use, faces the skin of a subject.
3. The device according to claim 1, which further includes an energy source selected from the group consisting of: a magnet; bipolar magnet; bimetallic plate, bioceramic bead and a battery, and wherein the device is placed in proximity to the skin of a subject in need of enhanced sexual function.
4. The device according to claim 1, which includes at least one bioceramic bead for emitting infrared rays to the skin.
5. The device according to claim 1, wherein the at least one energy source is at least one discrete region of the device.
6. The device according to claim 1, wherein the at least one discrete region of the device has a width/diameter of at least about 0.1 centimeter to about 1.0 centimeter and a height of at least about 0.1 centimeter to about 10.0 centimeter.
7. The device according to claim 1, wherein the at least one discrete region of the device has a width/diameter of at least about 0.1 centimeter to about 0.5 centimeter and a height of at least about 0.1 centimeter to about 0.5 centimeter.
8. The device according to claim 1, wherein the at least one discrete region of the device has width/a diameter of at least about 0.1 centimeter and a height of at least about 0.1 centimeter.
9. The device according to claim 1, wherein the at least one discrete region of the device has a width/a diameter of about 0.5 centimeter diameter and about 0.3 centimeter height.
10. The device according to claim 1, wherein the at least one energy source is a magnet with a magnetic flux density of at least about 500 – 15,000 gauss.
11. The device according to claim 1, wherein the at least one energy source is a magnet with a magnetic flux density of at least about 5,000 – 15,000 gauss.
12. The device according to claim 1, wherein the at least one energy source is a magnet with a magnetic flux density of at least about 5,000 – 9,000 gauss.

13. The device according to claim 1, wherein the at least one energy source is a magnet with a magnetic flux density of at least about 9,000.
14. The device according to claim 1, wherein the at least one energy source is a magnet containing germanium.
15. The device of claim 1, wherein the cuff has a gap to allow expansion of the cuff.
16. The device of claim 15, wherein the cuff further comprises an adjustable, self-closing clip.
17. The device of claim 15 or claim 16, wherein the cuff has a length extending toward the penile glans a distance of at least about 1 millimeter to about 50 millimeters.
18. The device of claim 15 or claim 16, wherein the cuff has a length extending toward the penile glans a distance of at least about 1 millimeter to about 25 millimeters.
19. The device of claim 15 or claim 16, wherein the cuff has a length extending toward the penile glans a distance of at least about 1 millimeter to about 10 millimeters.
20. The device according to claim 1, further comprising at least one temperature-sensing element.
21. The device according to claim 20, wherein the temperature-sensing element is a temperature sensitive crystal for indicating a change in the local blood flow or metabolism of a subject.
22. A method of treating a subject in need of enhanced sexual function, the method comprising positioning a device of titanium metal around the penis and exposing at least one region of the penis to a magnet forming part of the device.
23. The method according to claim 22, in which the device is placed so that the southern pole of the magnet is facing the skin of the subject in the said region.
24. The method according to claim 23, which includes exposing the penis to infrared rays.
25. The method according to claim 24, wherein the penis is exposed to far infrared radiation emitted by bioceramic beads forming part of the device.
26. The method according to any one of claims 22 to 25 inclusive, wherein the at least one region is an M-point.
27. The method according to claim 26, wherein the M-point is contacted with the south pole of at least one magnet.